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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/380,773 09/03/99 HEIN

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EXAMINER

HM12/1022

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ART UNIT

PAPER NUMBER

1652

DATE MAILED:

10/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/380,773

Applicant(s)

HEIN ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 24, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 1-37, 62 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

The amendment filed on September 24, 2001 has been entered.

Claims 1-63 are pending.

Election/Restrictions

Applicant's election with traverse of Group III (claims 38-61) in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the instant invention is drawn to a single nucleotide sequence co-expressing a PHA synthase and a fatty acid:acyl-CoA transferase in a single nucleic acid construct and that the reference of Dennis et al. does not teach a single nucleic acid fragment expressing both the PHA synthase and a fatty acid acyl-CoA transferase. This is not found persuasive because the reference of Dennis et al. does teach a single vector construct encoding the polyhydroxyalkanoate biosynthetic pathway and the succinic semialdehyde metabolic pathway (Column 3, lines 62-65 and claim 8 on Column 26). Further, Group III is drawn to a method of using a cell producing the two enzymes and does not necessarily read on a single nucleic acid fragment co-expressing the two enzymes. Therefore, there is no special technical feature linking Group I and Group III.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-37 and 62-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 38 is drawn to a method of preparing a polyester using a cell producing polyhydroxyalkanoic acid (PHA) synthase gene and a fatty acid acyl-coenzyme A transferase gene. Therefore, this claim encompasses a method using a genus of PHA synthase and a genus of fatty acid acyl-coenzyme A transferase from any source and with any structure. The specification only teaches one PHA synthase gene from *Alcaligenes eutrophus* of SEQ ID NO:1 and one fatty acid acyl-coenzyme A transferase gene from *Clostridium kluyveri* of SEQ ID NO:2. The representative number of species from each genus is one and a description of only one member of the genus is not representative of all the species of the genus. Therefore, the specification does not disclose the identifying characteristics or structural properties other than the functionality of being a PHA synthase gene and a fatty acid acyl-coenzyme A transferase gene.

Claims 44-48 limit claim 1 to an *A. eutrophus* phaC polyhydroxyalkanoic acid (PHA) synthase gene and a *C.kluyveri* orfZ 4-hydroxybutyric acid (4-HB) acyl-coenzyme A transferase gene. However, the claims are drawn to a genus of PHA synthase and a

genus of 4-Hb Co-A transferase gene with any structure. The specification only discloses one member from each genus, SEQ ID NO:1 and 2. One member of this genus is not representative of the species that have different structures but the same function.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 38-61.

Claims 38-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of preparing a polyester using PHA synthase gene of SEQ ID NO:1 and a 4-HB Co-A transferase gene of SEQ ID NO:2, does not reasonably provide enablement for a method of preparing a polyester using a PHA synthase gene and 4-HB Co-A transferase gene different from SEQ ID NO:1 and 2, respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)

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considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Although the specification teaches a method of preparing a polyester using a PHA synthase gene from *A. eutrophus* of SEQ ID NO:1 and one fatty acid acyl-coenzyme A transferase gene from *Clostridium kluyveri* of SEQ ID NO:2, it lacks guidance for a method using PHA synthase or fatty acid acyl-coenzyme A transferase from any source. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Therefore, one of ordinary skill would require guidance beyond that provided by the specification in order to prepare polyesters with a PHA synthase gene and 4-HB Co-A transferase gene with structures different from SEQ ID NO:1 and 2, respectively. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 38-61, the phrase "cell capable" or "the cell is further capable" is unclear because cells produce the enzymes mentioned in the claims naturally or can be engineered to produce the said enzymes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 38-42 and 44-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Dennis et al.

Dennis et al. (U.S. Patent No. 6,117,658) teach a method of preparing poly(4-hydroxybutyric acid), poly(3-hydroxybutyric acid) and poly(3-hydroxybutyric acid-co-4-hydroxybutyric acid) using a cell expressing an *Alcaligenes eutrophus* phaC polyhydroxyalkanoic acid synthase gene and a *Clostridium kluyveri* orfZ 4-hydroxybutyric acid acyl-coenzyme A transferase gene (Figure 1, Column 6, line 4 through Column 7 line 18 and Column and Column 8, line 63 through Column 9, line 39).

Regarding claims 39-42, Dennis et al. also teach a method for preparing a polyester with a plant cell and a bacterial cell, *Escherichia coli*, transformed with the said synthase and transferase gene (Column 18, line 1 through Column 23, line 6).

Dennis et al.

Regarding claims 49-51, Dennis et al. teach a method of producing a polyester with glucose, 1,4-butanediol, 4-hydroxybutyric acid and molecular oxygen in the culture medium (Column 10, lines 11-25 and Column 11, lines 1 through 43).

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Regarding claims 52-56, Dennis et al. also teach a method of preparing a polyester with a cell producing a succinyl-coenzyme A:coenzyme A transferase protein, a succinate-semialdehyde dehydrogenase, and a 4-hydroxybutyrate dehydrogenase, a succinate-semialdehyde dehydrogenase. Therefore, the teachings of Dennis et al. anticipate claims 38-42 and 44-61.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 38-39 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dennis et al. in view of Greener et al.

Dennis et al. teach a method of preparing a polyester with an *Escherichia coli* cell producing a polyhydroxyalkanoic acid synthase protein and a fatty acid-acyl-coenzyme A transferase protein, as discussed above.

The difference between the reference of Dennis et al. and the instant invention is that the reference of Dennis et al. does not teach a method using an *E. coli* strain XL1-Blue.

Greener (U.S. Patent No. 5,512,468) teach that *E. coli* strain XL1-Blue cells have high transformation efficiencies (Column 8, line 62 through Column 10, line 62).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to prepare polyesters using a XL1-Blue cell producing the polyhydroxyalkanoic acid synthase protein and a fatty acid-acyl-coenzyme A transferase. XL1-Blue cells have high transformation efficiency, resulting in an increased production of enzymes. One of ordinary skill in the art would have had a reasonable expectation of success since transforming XL1-Blue cells is routinely performed in the art.

No claims are allowed.

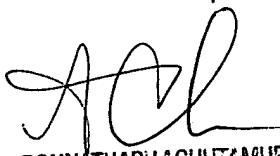
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

October 18, 2001



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